Notice of Allowability	Application No.	Applicant(s)	
	09/724,570	SCHENK, DALE B.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *20 August 2004*.

2. ☒ The allowed claim(s) is/are *58-69*.

3. ☒ The drawings filed on *29 December 2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 12.29.03 10.25.04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 19 May 2004 has been received and entered in full.

2. The Examiner notes that Applicant did not file an Appeal Brief on 14 November 2003 but an "AMENDMENT/ARGUMENT AFTER NOTICE OF APPEAL". The Office was mistaken to take the arguments as an Appeal Brief. However, the fact remains that the Amendment and Arguments filed on 14 November 2003 were received and entered in full. Further, the Examiner *withdrew* finality to address said amendments and arguments, thus the last Office Action was a Non-Final Rejection (21 January 2004).

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. All Rejections and Objections in the previous Office Action (21 January 2004) are hereby *withdrawn* and/or *moot* in view of the instant Examiner's Amendment.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

6. In the Title:

PASSIVE IMMUNIZATION OF ASCR FOR PRION DISORDERS

7. In the claims:

Claims 1-57 (Cancelled)

Claim 58 (New) A method of therapeutically treating a patient suffering from a prion disorder associated with AScr, comprising administering to the patient an effective dosage of a human, chimeric, or humanized antibody or antibody fragment thereof that specifically binds to AScr, wherein the isotype of the antibody is human IgG1, and thereby therapeutically treating the disorder.

Claim 59 (New) The method of claim 58, wherein said effective dosage is characterized by a level in the patient of a serum amount of immunoreactivity against AScr that is at least about four times higher than a serum level of immunoreactivity against AScr measured in a pre-treatment control serum sample.

Claim 60 (New) The method of claim 58, wherein the antibody or antibody fragment is administered with a carrier as a pharmaceutical composition.

Claim 61 (New) The method of claim 58, wherein the antibody or antibody fragment is administered intraperitoneally, orally, subcutaneously, intramuscularly, intranasally, topically, or intravenously.

Claim 62 (New) The method of claim 58, wherein the antibody or antibody fragment is administered in multiple dosages over a period of at least six months.

Claim 63 (New) The method of claim 58, wherein the antibody or antibody fragment is administered as a sustained release composition.

Claim 64 (New) A method of prophylactically treating a susceptible to a prion disorder associated with AScr, comprising administering to the patient an effective dosage of a human, chimeric, or humanized antibody or antibody fragment thereof that specifically binds to AScr, wherein the isotype of the antibody is human IgG1, and thereby effecting prophylaxis of the disorder.

Claim 65 (New) The method of claim 64, wherein said effective dosage is characterized by a level in the patient of a serum amount of immunoreactivity against AScr that is at least about four times higher than a serum level of immunoreactivity against AScr measured in a pre-treatment control serum sample.

Claim 66 (New) The method of claim 64, wherein the antibody or antibody fragment is administered with a carrier as a pharmaceutical composition.

Claim 67 (New) The method of claim 64, wherein the antibody or antibody fragment is administered intraperitoneally, orally, subcutaneously, intramuscularly, intranasally, topically, or intravenously.

Claim 68 (New) The method of claim 64, wherein the antibody or antibody fragment is administered in multiple dosages over a period of at least six months.

Claim 69 (New) The method of claim 64, wherein the antibody or antibody fragment is administered as a sustained release composition.

8. Authorization for this examiner's amendment was given in a telephone interview with Rosemaire Celli on 8 November 2004.

9. Additional claims are required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on Rosemaire Celli on 8 November 2004 authorized the Director to charge Deposit Account No. 20-1430 the required fee of $340 for these additional claims and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Summary

10. Claims **58-69** are hereby allowed.

11. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
November 8, 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER